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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,439	01/14/2005	Michio Mineshima	NPR-159	9055
7590 Kubovcik & Kubovcik The Farragut Building Suite 710 900 17th Street NW Washington, DC 20006				
			EXAMINER KOHARSKI, CHRISTOPHER	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 08/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,439

Applicant(s)

MINESHIMA ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/14/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/30/2008 has been entered.

Response to Amendment

Examiner acknowledges the reply filed 04/30/2008 in which claims 1, 7 and 9 were amended. Currently claims 1-2, and 5-11 are pending for examination in this application.

Specification

The disclosure is objected to because of the following informalities: The disclosure cites "Japanese Patent Publication No. 3-54591", this does not appear to a valid publication number or reference number.

Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the amended subject matter (claims 1 and 7, 9) reciting the fluid pumps and pump components must be shown or the feature(s) canceled from the claim(s) (i.e. no fluid pumps or specific

structures are shown via the drawings in the dehydration mechanism). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobsen et al. (USPN5,141,493). Jacobsen et al. discloses a closed circuit peritoneal dialysis system.

Regarding claims 7-11, Jacobsen et al. discloses a peritoneal dialysis system (Figures 1A-1B) comprising: a catheter (12) capable of injecting and discharging peritoneal dialysate in an abdominal cavity of a patient (patient, Figure 1A); a peritoneal dialysate circuit (primary circuit) external of the patient connected to the catheter (12); and a dialyzer provided in the peritoneal dialysate circuit (primary circuit, 1A); said dialyzer comprising a hemodialysate circuit (secondary circuit, 1B) connected via a hollow fiber membrane (24), characterized in that a means capable (196, 160, 28) of measuring a conductive osmotic agent concentration in peritoneal dialysate is provided in the peritoneal dialysate circuit on the side of the end at which the catheter (12) is connected for removal of water in the peritoneal dialysis circuit (cols 4-5) using microprocessor (220) controlled pumps (192, 16, 72) (Figures 1A-1B) with a calculating unit (cols 6-7) (Figure 1); and wherein the hemodialysate outflow from the dialyzer will be larger since the hemodialysate circuit removes water from the main patient circuit via the pump (16, 192) and the pressure valve (36) (col 4, ln 55-70).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 5-6 are rejected under 35 U.S.C 103(a) as being unpatentable over Jacobsen et al. (USPN5,141,493) in view of Karoor et al. (US2003/0105424). Jacobsen et al. meets the claim limitations as described above except the multi-pump hemodialysate circuit.

However, Karoor et al. teaches a method and composition for removing toxins in dialysis.

Regarding claims 1-2 and 5-6, Karoor et al. teaches dialysis system (Figure 1) comprising: a catheter (24) capable of injecting and discharging fluid in an abdominal cavity of a patient (patient, Figure 1A); a primary circuit (10) external of the patient connected to the catheter (24); and a dialyzer provided in the primary circuit; said dialyzer comprising a hemodialysate circuit (12) connected via a hollow fiber membrane (20), the dialyzer system capable of removal of water in the peritoneal dialysis circuit ([0014]) using a pump (pump near NH3 filter) provided in a hemodialysate inflow channel to the dialyzer and a pump (lower pump near dialysate bags) provided in a hemodialysate outflow channel from the dialyzer, the pumps being driven so that a flux

in the pump on the outflow channel side is larger than a flux in the pump on the inflow channel side (via the removal of water and toxins from the dialyzer, [0014], Figures 1-7).

At the time of the invention, it would have been obvious to replace the single pump (192) of Jacobsen et al. with the dual pump assembly in order to allow for controlled fluid flow and increased fluid pressure required for removal of larger molecules through the dialyzer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Karoor et al. ([0001-0010]).

Response to Arguments

Applicant's arguments with respect to claims 1-2 and 5-6 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 04/30/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that prior art reference does not disclose the wherein said dehydrating mechanism is one in which an amount of hemodialysate outflowing from the dialyzer is made to be larger than an amount of hemodialysate inflowing into the dialyzer.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Jacobsen et al. (USPN5,141,493) reference does disclose the hemodialysate outflow from the dialyzer (24) will be larger since the

hemodialysate circuit removes water from the main patient circuit via the pumps (16, 192) and the pressure valve (36) (col 4, ln 55-70).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 8/21/2008

Application/Control Number: 10/521,439
Art Unit: 3763

Page 8

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Luccesi/
Supervisory Patent Examiner, Art Unit 3763